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Food Safety Assessment Program

Assessment Report of the Canadian Food Inspection Agency Activities Related to the Safety of Imported Fresh Fruits and Vegetables

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Executive Summary

In April 1997 the *Canadian Food Inspection Agency Act* established the Canadian Food Inspection Agency, reporting to the Minister of Agriculture and Agri-food. Health Canada is responsible for assessing the effectiveness of the Agency's activities related to food safety. The objective of this assessment was to determine the effectiveness of the Canadian Food Inspection Agency's programs and activities related to the safety of imported fresh fruits and vegetables. We examined the program design, implementation and enforcement actions as well as the results of food safety activities in the Agency's Fresh Fruit and Vegetable Program and the Consumer Food Products Program for the period between April 1, 1997 and March 31, 2000. Starting in late 1999, the Agency was concurrently carrying out a review of programs transferred from Health Canada and Industry Canada when the Agency was created (including the Consumer Food Products Program). As a result of this review, the Consumer Food Products Program was re-designed and re-named the Food Safety Investigation Program on March 28, 2000.

Key Observations

Knowledge of the products entering Canada is fundamental to controlling imports. Better use of the information on imports that is available to the Agency could assist in selecting samples for analysis, in identifying importers of high-risk produce for inspection and in conducting investigations. The Agency has devoted much effort to developing an electronic information processing system that captures and retrieves information on any specific meat, egg or fish import and plans to include fresh fruits and vegetables in the future.

The Fresh Fruit and Vegetable Program and the Consumer Food Products Program used different strategies and activities to control imported fresh fruits and vegetables. Both programs were implementing new strategies to address emerging issues in imported fresh fruits and vegetables. A better integration of food safety strategies and use of available import information would be beneficial and could lead to increased assurance in the safety of imported fresh fruits and vegetables. Moreover, the Agency should continue to work towards an Integrated Inspection System that will integrate strategies across programs and commodities including the inspection and control of imports.

The Fresh Fruit and Vegetable Program collects and analyses thousands of imported fresh fruits and vegetables each year for chemical residues and microbiological pathogens. The Agency inspectors could collect samples at a greater variety of destination points and better fulfill workplan requirements – collect samples for the required commodity from the required country – through the use of import documentation. The Agency's chemical residue monitoring workplan is partially fulfilled by the operational areas and private laboratories are used to address shortfalls and further fulfill the sampling plan.

One of the strategies employed by the Consumer Food Products Program was to inspect fresh fruit and vegetable importing establishments. Due to other food safety priorities, this strategy was not extensively implemented. A small number of importing establishments were inspected and these inspections were seldom complemented by sampling. The Consumer Food Products Program rated the compliance of each import establishment inspected; however the import establishments that had received an unsatisfactory compliance rating were not always re-inspected as planned.

In the Fresh Fruit and Vegetable Program, improvements are needed to ensure that all violations of regulatory requirements identified through monitoring samples are followed up by appropriate actions. It is essential that inspectors be notified of violations as quickly as possible so that future shipments of suspect products are identified and sampled accordingly. Appropriate measures need to be taken to prevent the marketing of fresh fruits and vegetables that have a history of non-compliance, unless the products are verified as meeting Canadian requirements. Since importers are not required to notify the Agency of the arrival of future shipments, it is more difficult for the Agency to monitor imports for products that are identified on the compliance list. These activities could benefit from access to timely, reliable import information that will assist in the identification of fresh fruits and vegetables on the surveillance or compliance lists.

The Consumer Food Products Program appropriately investigated and determined the compliance status of food safety incidents (e.g., consumer complaints) related to imported fresh fruits and vegetables in all cases that we reviewed. When notified of a food-borne disease outbreak associated with imported fresh fruits and vegetables, officials of both the Fresh Fruit and Vegetable Program and the Consumer Food Products Program became key members of the investigative team and participated in trace-back investigations. The Agency has written draft procedures for trace-back investigations, and training for inspectors is planned after the trace-back manual is completed.

Conclusion

In summary, various aspects of the Fresh Fruit and Vegetable Program and the Consumer Food Products Program were working as intended, however, some key improvements are required in order to increase their effectiveness. In particular, improving the access to and use of available information on imported products, especially those with a history of non-compliance, as they enter Canada would clearly lead to increased assurance in the safety of imported fresh fruits and vegetables.

Introduction

1 Canadians who want the health benefits of a diet rich in fresh fruits and vegetables depend on global markets to provide year-round availability. The risks associated with the consumption of fresh fruits and vegetables are often considered low. However, recent food-borne illness linked to produce (e.g., outbreaks associated with *Cyclospora*), and the perception that fresh produce is contaminated with pesticides, have increased consumer awareness of the potential contamination of fresh fruits and vegetables. The Bureau of Food Safety Assessment has chosen to assess the effectiveness of the Canadian Food Inspection Agency's food safety programs for imported fresh fruits and vegetables.

2 In this assessment we have considered fresh fruits and vegetables to include whole fresh products, nuts and pre-cut fresh products. Import requirements for these products are covered in two acts and regulations. The *Food and Drugs Act* has general application to the safety, composition and nutritional quality of all food sold in Canada by regulating the import, manufacture, packaging, preparation, preservation and storage of food. It covers all fresh fruits and vegetables as defined for this assessment. The *Canada Agricultural Products Act* is based on the federal authority to regulate interprovincial and international trade and commerce. Its *Fresh Fruits and Vegetables Regulations* cover whole products and nuts. Details of the specific legislative requirements for the importation and safety of fresh fruits and vegetables are listed in appendix II. To fulfill its responsibilities under these two Acts, the Canadian Food Inspection Agency established two distinct programs: the Fresh Fruit and Vegetable Program and, when this assessment was conducted, the Consumer Food Products Program.

3 The Fresh Fruit and Vegetable Program covers commodities which are regulated under both the *Canada Agricultural Products Act* and the *Food and Drugs Act* and their Regulations, i.e. whole fresh fruits, whole fresh vegetables, and nuts. Its import control strategies include verifying import documentation at the port of entry and sampling and analysing products as per the Program's work plan requirements. It also samples imported pre-cut fresh fruits and vegetables for microbiological contaminants even though these products are regulated solely under the *Food and Drugs Act and Regulations*.

4 The Consumer Food Products Program was enforcing the *Food and Drugs Act and Regulations* for imported fresh fruits and vegetables during its inspection activities. Its main import control strategies included inspecting importing establishments and sampling suspect products. On March 28, 2000, following an Agency program review, the Agency re-designed the Consumer Food Products Program. Agency officials indicated that the Program, now called the Food Safety Investigation Program, enforces the safety and nutritional quality provisions of the *Food and Drugs Act* by investigating consumer and industry complaints and taking appropriate enforcement actions to contribute to the safety of the food supply. The program also undertakes preventative measures, using a risk based approach, to promote compliance with the provisions of the *Food and Drugs Act*. The Fresh Fruit and Vegetable Program was not affected by this re-design.

5 At the time of the assessment, the Canadian Food Inspection Agency was reviewing the legislation it is responsible for enforcing. The Task Force on Legislation recommended a strengthening of the Agency's existing legal authority with respect to controlling imported products. According to the Task Force, "Improved document control, refusal of entry provisions for products that fail to comply with Canadian requirements, as well as improved provisions for detainment of product, should all be reflected in modernized legislation." The Task Force also recommended enforcement and compliance provisions, such as the authority to designate points of importation and the conditions for entry.

Objectives and Scope

6 The objective of this assessment was to determine the effectiveness of the Agency's programs and activities related to the safety of imported fresh fruits and vegetables. We examined the design, implementation and results of the Agency's activities related to food safety both before and after importation, as well as enforcement actions taken in response to risks associated with imported fresh fruits and vegetables. We assessed the food safety activities that took place between 1 April 1997, the date the Agency was formed, and 31 March 2000.

7 The assessment was conducted at the Canadian Food Inspection Agency Headquarters and in the Quebec, Ontario and Western operational areas. We visited Agency offices, three ports of entry, and three import warehouses where imported fresh fruits and vegetables are sampled. We interviewed key personnel, reviewed program manuals and files, observed field work and assessed the Agency's activities and outputs related to imported fresh fruits and vegetables. For more information on this assessment, refer to "About the Assessment" in Appendix I.

8 This assessment covers activities undertaken under two programs, the Fresh Fruit and Vegetable Program and the Consumer Food Products Program. As noted above, since March 28, 2000, the later program was re-designed and re-named the Food Safety Investigation Program. We anticipate that some of the findings from the assessment of the Consumer Food Products Program will provide useful information to the managers of the Food Safety Investigation Program. The Food Safety Investigation Program will implement a new approach to deliver its mandate. We are not commenting on the new approach in this assessment. We will assess the effectiveness of this new approach in monitoring and controlling the safety of imported fresh fruits and vegetables during our follow-up to this assessment.

Observations and Recommendations

Use of Import Documentation

General Remarks

9 Knowledge of the products entering Canada is fundamental to controlling imports. Timely and accurate information on the volumes, country of origin and importers of specific fresh fruits and vegetables is a factor that influences program design, planning for sampling and inspection, implementation of plans and enforcement. Where information on the importers and volume of suspect fresh fruits and vegetables are known, the Agency and the industry can respond more effectively to food-borne illness outbreaks.

10 Both programs can identify hazards and risks from several sources: laboratory analyses; inspection compliance reports; consumer/trade complaints; and notification from other regulatory agencies such as Health Canada, provincial authorities, and the United States Food and Drug Administration. Imported fresh fruits and vegetables that were linked to food-borne disease outbreaks, had a history of excess levels of chemical residues, or were contaminated with pathogenic micro-organisms were given a higher priority for sampling and inspection.

11 When imported fresh fruits and vegetables arrive at ports of entry import documents are presented to Revenue Canada Customs[1] Border Services. Specific documents are required, in addition to customs invoices, for produce regulated under the *Canada Agricultural Products Act*. In these cases, under a memorandum of understanding (MOU), Revenue Canada Customs ensures that all required documents, including the Confirmation of Sale, accompany import shipments and are complete. The Customs D-19-1-1 Memorandum empowers Revenue Canada Customs to release for sale into Canada imported produce other than those high-risk fresh fruits and vegetables identified in Border Lookouts or produce specified in the memorandum. For the products regulated only under the *Food and Drugs Act*, imports do not require a Confirmation of Sale or any other specific import documentation besides the normal customs invoices presented to Customs for all import shipments. Customs likewise releases all imported produce unless they are identified in Border Lookouts.

12 When a produce is the subject of a Border Lookout, Customs is requested to forward the import documents of specified fresh fruits or vegetables to one of the Agency's Import Service Centres. When contacted by Customs, the Import Service Centre reviews the targeted shipment's documentation and subsequently informs the Operational Area office that is responsible for enforcement activities. The Canadian Food Inspection Agency, in an effort to facilitate the flow of imports and to put control measures in place to enhance the safety of imported food products, has established three Import Service Centres – one each in Montreal, Toronto and Vancouver. These Centres provide 20 hours of service, seven days a week across the country, and are accessible to importers by fax and by electronic means.

[1] Revenue Canada Customs, as of 1 November 1999, became the Canada Customs and Revenue Agency.

13 The Agency has devoted much effort to developing an electronic information processing system – Import Control and Tracking System that captures and retrieves information on any specific meat, egg or fish shipment. This system will track the location, status and final decision on each imported commodity within a shipment. Eventually it will be available to all commodities, including fresh fruits and vegetables.

Fresh Fruit and Vegetable Program

14 The Fresh Fruit and Vegetable Program obtains information about the fresh fruits and vegetables entering Canada from import documents such as the Confirmation of Sale required for the products they regulate, or from summary reports (i.e., Statistics Canada import data and/or Revenue Canada Customs special requested reports) based on information taken directly from Revenue Canada Customs' data. We assessed whether the Agency forwards fresh fruit and vegetable import documents (Confirmation of Sale) to inspection staff and use them to select imported produce for sampling.

15 We found that the Fresh Fruit and Vegetable Program does not consistently receive import documents from Revenue Canada Customs, and the inspection staff does not use this information to select samples for analysis. Information contained in import documents can help to identify produce required for the Fresh Fruit and Vegetable Program's monitoring, surveillance or compliance sampling and analysis. The Agency has informed us that a procedure is being developed that will address this issue in all the operational areas. We noted that the Agency does use Revenue Canada Customs summary reports in investigations to trace back suspect imported fresh fruits or vegetables.

16 The Customs Memorandum D19-1-1 requires Revenue Canada Customs Border Services to collect and forward the required import documents to the Agency according to established procedures. Currently these procedures consist of verbal agreements between individual Agency offices and local Customs' ports of entry. The Fresh Fruit and Vegetable Program has no national procedure or policy for collecting or distributing import documents, or for the use of these documents in selecting shipments for sampling. Consequently, we found that at two of the three ports of entry visited copies of import documents were only sometimes forwarded to the Fresh Fruit and Vegetable Program:

- Port A had a systematic process whereby all documents are forwarded by courier to a central Customs office. This office sent import documents routinely to the Agency's Import Service Centre, which in turn forwarded them to the Fresh Fruit and Vegetable Program.
- At Port B import documents were not forwarded to the Agency.
- At Port C, Customs officials collected import documents and delivered them to the Agency's Import Service Centre. However, the documents were not subsequently sent to the Fresh Fruit and Vegetable Program.

17 One operational area has tried to improve the collection and distribution of import documents by determining the number of fresh fruit and vegetable shipments based on Customs summary reports. They found that approximately 30 percent of the import documents were being forwarded to the Agency. Subsequent visits to area ports of entry and meetings with Customs officers resulted in an increase to approximately 50 percent in the number of import documents collected and sent to the Agency. The Agency has informed us that a procedure is being developed that will address this issue in all the operational areas.

Consumer Food Products Program

18 There is no specific import document required for products regulated solely under the *Food and Drugs Act*. However, information regarding importers of pre-cut fresh fruits, pre-cut fresh vegetables, and nuts can be obtained by way of the customs import invoices that accompany all shipments, or through import data summary reports requested from Revenue Canada Customs. Information contained in customs import invoices can help the Consumer Food Products Program to identify new importers and importers of high-risk priority produce, and to maintain an up-to-date database of importers and the products they import. This database, the Food Establishment List, was used to select importing establishments for routine inspection and to target importing establishments for investigations when hazards have been identified in imported produce. We assessed whether import documents are forwarded to the Consumer Food Products Program's inspectors and used to select importers for inspection and identify suspected non-compliant produce for sampling.

19 We found that copies of import documents (invoices) were forwarded by Customs to the inspection staff in one of three Consumer Food Products Program operational area offices visited and used to identify importers of high-risk priority produce for inspection or sampling. Import documents or summary reports were not routinely used to identify new importers or to update the importer information in the Food Establishment List. The Food Establishment List was not always accurate with respect to the type of commodities imported by each establishment. Because importers and the products they import are constantly changing, and because import establishments are not registered and there is no legislative requirement for them to provide information to the Agency, maintaining the List is a difficult task. Moreover, Agency staff indicated that this was not a priority activity for the Consumer Food Products Program. In fact, with the transition to the Year 2000, the Food Establishment List is being replaced by the Canadian Food Inspection Agency's Client Management System, which will incorporate the importer information currently contained in the Food Establishment List. In special situations where an importer of non-compliant products needs to be identified, the Consumer Food Products Program uses Revenue Canada Customs summary reports.

20 The Customs D-19-1-1 Memorandum does not include produce regulated solely under the Food and Drugs Act and Regulations, and as such there are no instructions to Customs regarding import document requirements or release requirements. We noted, however, that one inspection office had made a verbal agreement with local ports of entry to collect and forward to the inspection office the customs invoices which accompany the imports they regulate. This information was used successfully to identify suspect importers/products, (e.g., nuts with suspected aflatoxin above the acceptable limit, imported from countries or by importers with a history of non-compliance) and to target them for sampling.

Recommendation

The Canadian Food Inspection Agency should implement a mechanism for collecting information on imported fresh fruits and vegetables for use in their respective programs. In the interim, the Fresh Fruit and Vegetable Program should continue discussions with the Canada Customs and Revenue Agency to facilitate the exchange of import documents.

Agency Response

CFIA is currently in the process of developing and implementing the Import Documentation Tracking and Verification Program. This program is a management tool that describes the procedures for:

a. establishment of roles and responsibilities between CFIA and the Canada Customs and Revenue Agency,
b. verification of import documentation by CFIA staff,
c. tracking distribution of import documentation,
d. review of import documentation by Canada Customs and Revenue Agency staff, and
e. compliance verification of import documentation.

To assist in the management of the Import Documentation Tracking and Verification Program, CFIA is currently developing a computerized system to sort data obtained from the Canada Customs and Revenue Agency. This system will produce summary reports of imported fresh produce shipments which will be used to analyse and track import documentation.

Furthermore, CFIA has initiated discussions with the Canada Customs and Revenue Agency on updating the national policy and procedures for dealing with import documentation.

Design of Programs to Control Imports and Monitor Imported Products for Compliance with Legislative Requirements

General Remarks

21 The Canadian Food Inspection Agency has many inspection programs to address the imported products that it regulates. These import control programs were developed by different departments under various legislation before the Agency was formed. They employ different strategies and activities to control and monitor products imported into Canada. The Agency is working towards an Integrated Inspection System[2] that will address key horizontal program strategies, such as the inspection and control of imported commodities.

22 We reviewed the strategies used by the Fresh Fruit and Vegetable Program and the Consumer Food Products Program to manage risks in imported fresh fruits and vegetables and assessed whether the designed programs and planned activities cover the applicable legislative requirements and control the safety of imported fresh fruits and vegetables. As described below, the strategies employed in the two programs were very different. They both included a variety of activities that were sometimes distinct and that sometimes overlapped. Also, they both had limitations. We believe that a better integration and use of the import control strategies and information would be beneficial, and could lead to increased assurance in the safety of imported fresh fruits and vegetables.

Fresh Fruit and Vegetable Program

23 The Fresh Fruit and Vegetable Program's main import control strategy is to sample and analyse products at destination, as per the Program's workplan requirements. Imported products are also controlled by verifying import documentation, prohibiting entry of products at border points through Border Lookouts, by conducting trace-back investigations of suspect non-compliant produce, and in special circumstances by assessing foreign countries' inspection systems. The Program has also participated in an intensive physical examination of shipments at ports of entry (Import Blitz).

24 One Agency strategy to address recent emerging microbiological issues in fresh fruits and vegetables is to develop codes of practice internationally through the CODEX Committee on Food Hygiene or nationally through the Horticultural Code Subcommittee of the Canadian Food Inspection System Implementation Group (CFISIG). Upon adoption by CODEX or CFISIG, both domestic and imported produce and their suppliers may be assessed against these standards. The codes of practice under development include: the Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables; the Code of Practice for Minimally Processed Ready-to-Eat Vegetables; and the Code of Practice for the Hygienic Production of Sprouted Seeds and Beans.

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[2] An Integrated Inspection System as defined by the Agency is "a harmonized approach for all food commodities, where industry is responsible for controlling its products and processes in compliance with the recognized standards and regulations, and government is responsible for verifying the effectiveness of industry's control systems".

25 The Fresh Fruit and Vegetable Program, with the assistance of Health Canada, has used the foreign country assessment strategy to help develop import policies for raspberries and blackberries from Guatemala. Section 3.1(1)e of the *Fresh Fruits and Vegetables Products Regulations* (see Appendix II) focusses on the quality of water used in the preparation of imported fresh fruits and vegetables. Water has been identified as a potential source of contamination of imported fresh fruits and vegetables. The Program monitors compliance with this regulatory requirement indirectly through microbiological sampling and analysis of imported produce. The traditional approach of end-product testing cannot produce a level of assurance of food safety equivalent to that achieved by process-oriented (Hazard Analysis Critical Control Point) controls at the source. The extent of control of critical points (eg., water quality) can be monitored most effectively at the production source. Where a food safety issue is identified, an agreement with the foreign regulatory agency to monitor and verify the safety of produce exported to Canada would be beneficial.

26 The Fresh Fruit and Vegetable Program strategy is to notify foreign shippers/growers and/or the foreign country when violations occur, so that corrective measures may be implemented at the source of the problem. The strategy of dealing with only the foreign stakeholders and not the Canadian importer as well, places the onus on the Program to identify future suspect imports and to verify that effective corrective measures were implemented. Without timely, reliable and accessible information on the produce that enters Canada, this is a difficult task. The Agency told us that, due to legislative concerns, Canadian importers of fresh fruits and vegetables do not have access to the compliance list which identifies the foreign commodity/supplier of high-risk products.

27 The Customs Memorandum D-19-1-1enables Customs Border Services to identify and refer non-complying importers or commodities where there is a risk of human health concerns or major compliance deviations. This is done through Border Lookouts which are initiated by the Canadian Food Inspection Agency and can be either electronic, linked to the Customs database, or written bulletins distributed to and posted at ports of entry. In either case, a Border Lookout is meant to be an exceptional measure for short-term action to address an immediate high-risk situation and/or a major infraction of the regulations. They are not intended to be used to administer Agency legislation on a day to day operational basis. The Border Lookout protocol, which standardizes procedures, directs that the number of Border Lookouts be kept to a minimum number. If a problem is foreseen to be long term, the D19-1-1 Memorandum is amended to indicate an action to be taken by Customs Border Services for this type of commodity.

28 We noted that between 1 April 1997 and 31 March 2000, the Fresh Fruit and Vegetable Program implemented national Border Lookouts for Guatemalan raspberries and blackberries because of parasites and Japanese fresh fruits and vegetables because of suspected radiation concerns. But other commodities regulated by the Program – such as imported parsley associated with an illness outbreak and other produce with a history of chemical residues in excess of accepted limits in Canada – have not been placed on Border Lookout.

29 We found that the current Border Lookout system has constraints. The Agency indicated that not all Border Lookouts may be implemented as requested because they require a high degree of maintenance by Customs officials. For Border Lookouts linked to the Customs electronic database, the target must be associated with a specific importer. A new importer, or one that is not on the electronic database, will not be identified to Customs as suspect, and the potentially non-compliant product might enter Canada without being referred to an Import Service Centre. We found during our visits that Customs officers did not always have copies of the Agency's Border Lookouts posted at the ports of entry.

30 The clearance of import documents relies on the integrity and honesty of importers in their declarations. The Import Blitz activity, in which both programs participate, monitors compliance against regulatory requirements by physical examination of import shipments at the port of entry and by verification of the shipment's import declarations. The Import Blitz activity can educate importers and can train and maintain good relationships with Customs Border Services personnel; however, this activity is currently carried out in only one operational area. We reviewed twelve monthly reports and noted that Agency inspectors identified 64 infractions in 320 fresh fruit and vegetable import shipments that were examined during 64 Import Blitzes. The type of infractions noted in imported fresh fruits and vegetables include: incorrect country of origin declared; an incomplete list of the produce actually being imported; and no Confirmation of Sale.

Consumer Food Products Program

31 The Consumer Food Products Program's primary import control activity was inspection of importing establishments and sampling of suspect products. Other activities included: issuing Border Lookouts; traceback investigations; the investigation of food safety complaints; and food recalls. The Program also participated in an intensive physical examination of shipments at ports of entry (Import Blitz).

32 The main strategy employed by the Consumer Food Products Program was to evaluate the controls the importer had in place to prevent health hazards from occurring in its products. In contrast to the situation in the Fresh Fruit and Vegetable Program, the onus was placed on the importer to implement and maintain controls to ensure that the food products comply with the *Food and Drugs Act and Regulations*. The strategy was to focus on identified commodity problems and on importers with lower compliance rates. However, without timely, reliable and accessible import information on non-compliant importers and problem commodities, this was a difficult task.

33 In 1999 the Program initiated a new assessment approach to evaluate the controls that an industry sector has in place to meet the regulatory requirements and to address an identified hazard. One assessment, namely Labelling and Allergen Controls in the Food Import Sector, was conducted from May 1999 to February 2000. This resulted in a number of recommendations intended to help importers to improve the safety of the imported food products for consumers with food allergies. This new program strategy moved away from routine inspections of establishments and focussed on assessing and educating an industry sector.

34 The Border Lookout, as previously described in the Fresh Fruit and Vegetable Program section, is a risk-based approach to import control that the Consumer Food Products Program used to address high-risk products. Since 1 April 1997, the Consumer Food Products Program had determined that it was appropriate to implement a Border Lookout in one instance. A local or area Border Lookout was implemented by one operational area for pistachio nuts because of the possibility of aflatoxin contamination.

35 The Consumer Food Products Program participated in the Import Blitzes in one operational area. The import shipments examined during some of these blitzes included pre-cut fresh fruits, pre-cut fresh vegetables, and nuts. The infractions noted for these products in the Import Blitz reports we reviewed included incorrect labelling.

Recommendation

The CFIA should improve fresh fruit and vegetable import control through better integration of import control strategies and use of available information.

Agency Response

Agreed. CFIA has recently developed a national import policy to guide the integration of its various import inspection activities, including its controls, monitoring, and enforcement actions. The policy will provide the basis for the strategic approach to harmonize all agency import control activities. Import control activities will be enhanced by improvements to electronic import tracking systems and enhanced working arrangements with the Canada Customs and Revenue Agency. The Agency is currently engaged in consultations with Industry regarding the national import policy.

Estimating Risk, Developing Risk Management Options and Establishing Program Priorities

General Remarks

36 As the volume of imports increases, the Canadian Food Inspection Agency must identify and focus on the imported fresh fruit and vegetable products of highest priority for sampling and inspection and import control. We assessed whether the Agency estimates the risk inherent in the fresh fruits and vegetables being imported, develops risk management options, and establishes priorities for managing the food safety risks in its inspections and sampling plans. We reviewed the Fresh Fruit and Vegetable Program's planning process with respect to the Chemical Residue Monitoring and Microbiological Sampling Plans and the Consumer Food Products Program's planning process for importer inspections.

Fresh Fruit and Vegetable Program

Chemical Residue Sampling Plan

37 Chemical residue sampling is carried out in three phases: monitoring, surveillance and compliance. Monitoring information is gathered on the occurrence of chemical residues in import shipments chosen at random. Surveillance sampling is directed at specific products and shippers found during the monitoring phase to violate regulatory requirements. The intent is to determine if the problem is on-going by ensuring that five subsequent shipments are in compliance, and to initiate corrective actions. The compliance phase is designed to prevent the marketing of a food product known to be contaminated or adulterated by requiring a certificate of analysis for each shipment or by detaining the shipment while sampling and analysing at the expense of the importer.

38 The Agency pursues a policy of managing the Chemical Residue Sampling Plan according to the principles established in the manual *Comprehensive Five-Year Plan for Chemical and Biological Risk Management*. A risk assessment rating system is used to select commodities to be sampled. Results are compiled and assessed to determine the status of the program and changes in compliance rates, and to augment the available database, which is used to target commodities to be sampled and the analysis to be conducted annually. Inspectors are provided with sampling plans that indicate the required analyses, a target sampling date, the commodity/country target, a country-of-origin substitutions list and a number of discretionary samples. Once a problem has been identified through analysis of monitoring samples, the surveillance phase is implemented to target specific brands and growers/shippers. Identifying non-compliant products and taking steps to target future shipments with the same problem is part of a good import control system.

39 During the assessment, staff in each operational area expressed a need for increased communication and participation in the planning process, specifically, they stated that a better mutual understanding of the target dates, the number of samples required, the commodity and country priorities, and the risks associated with chemical residues would facilitate sampling.

Microbiology Sampling Plans

40 Whereas chemical residue risk assessment methodologies are based on toxicological considerations, the *Comprehensive Five-Year Plan for Chemical and Biological Risk Management* indicates that scientific risk assessment of food-borne microbial pathogens and parasitic organisms is based on epidemiological criteria. The Agency has taken the initiative to establish a formal approach by reviewing epidemiological data with Health Canada to determine the Agency's microbiological sampling priorities.

41 The sampling plans for chemical residues identify the commodity and analysis required as well as the country of origin, and -when appropriate- the commodity brand and shipper. Microbiological Sampling Plans lack a similar stratified approach: they identify only the produce to be sampled and the analysis required. When knowledge of microbiological food safety concerns from specific countries or regions exist, it could be useful to stratify the plan accordingly.

Consumer Food Products Program

Importer Establishment Inspection and Sampling

42 The National Workplan for importer establishment inspection and sampling provided an overview of the mandate, strategy, priorities and issues to be addressed by the Consumer Food Products Program operational areas. The operational areas decided on the number of importer inspections. Importing establishments found in the Food Establishment List database were prioritized by referencing the work specifications to determine the risk priority category for importers of different commodities. Each risk priority category had a recommended inspection frequency. With respect to fresh fruits and vegetables, pre-cut packaged vegetables because of microbiological risks and nuts and seeds because of aflatoxin concerns were in the highest risk priority category. The number of planned importer inspections and the selection of establishments for inspection were affected by factors such as the available inspection resources, establishment compliance history, complaints and previous recalls involving the establishment. In 1999-2000, Operations Branch developed regional, area and national workplans which indicated the planned numbers of inspections. The work was divided among the operational areas and ultimately among the inspectors.

43 Specific guidance for sampling commodities was found in the work specifications dealing with aflatoxin contamination of foods and microbiological examination of specific foods. During importer establishment inspections, it was the responsibility of the inspector, within the guidelines provided, to decide when to collect product samples. The work specifications, including the commodity/hazard/country tables for selecting samples, have not been regularly updated.

Recommendation

The Canadian Food Inspection Agency should increase operational area participation in the planning process for chemical residue monitoring.

Agency Response

CFIA chemical residue monitoring plans are science based. The planning process provides for risk estimations which in turn lead to a risk based ranking of monitoring priorities.

CFIA will facilitate operational participation in the development of the chemical residue monitoring plan through the use of information sessions. The sessions will exchange information concerning the development of the monitoring plan, the importance of meeting sampling plan requirements, commodity and country priorities and the risks associated with chemical residues.

Sampling and Inspecting in Accordance With The Level Of Risk and Workplan Requirements

44 We reviewed Agency practices related to sampling and inspection and analysed the coverage and fulfilment of workplans. We assessed whether the Fresh Fruit and Vegetable Program samples fresh fruit and vegetable shipments and whether the Consumer Food Products Program inspects importing establishments in accordance with the level of risk and workplan requirements. For the Fresh Fruit and Vegetable Program, the workplans were met in 1998/99 and were partially met in 1997/98 and 1999/2000. Several concerns related to the selection of samples for the Chemical Residue Monitoring Plan are identified below. For this reason, compliance rates must be interpreted with care. Improvements would result from a better use of import documents and summary reports. For the Consumer Food Products Program, workplans and intended inspection frequencies were far from being achieved: many importers of high-risk priority commodities were not inspected during the 31-month review period. Starting in late 1999, the Canadian Food Inspection Agency carried out a review of programs transferred into the Agency from Health Canada and Industry Canada. As a result of this review, this program has now been redesigned.

Fresh Fruit and Vegetable Program

Chemical Residue Sampling Plan

45 The purpose of the Fresh Fruit and Vegetable Program's Chemical Residue Monitoring Plan is to monitor the compliance of the food supply for chemical residues. It also collects information on different residues and commodity/country combinations. The information generated by the Chemical Residue Monitoring Plan and the Microbiological Sampling Plan is important in establishing trends, evaluating the risk of specific residues or foods, and identifying violations of the legislation and potential problem commodity/country/shipper combinations. Carrying out the sampling plan permits the Agency to concentrate on different residues and commodity/country combinations, and to discontinue sampling of those that show continuous compliance.

46 The national delivery of the Chemical Residue (Screening) Monitoring Plan for 1997-98, 1998-99 and 1999-2000 is summarized in the table below.

Chemical Residue Screening Monitoring Samples 1 April 1997 to 31 March 2000				
	97-98	98-99	99-2000	Total over 3 years
# Samples Planned	8,270	5,704	9,489	23,463
# Samples Collected by CFIA	4,520	4,452	4,366	13,338
# Samples Collected by Private Lab	2,764	1,390	2,911	7,065
# Samples Collected – Total	7,284	5,842	7,277	20,403
% Plan Delivered	88%	102%	77%	87%

87 percent of the planned samples were collected over this three-year period. The Agency's inspectors collected an average of 57 percent of the planned samples over the three-year period. Private labs were contracted to collect samples when shortfalls were detected in the collection of samples by Agency inspectors. Private labs collected an average of 30 percent of the planned samples.

47 The samples collected by private labs do not always adequately identify the product brand, grower/shipper and or country of origin needed to take appropriate action in the case of a violation. Information supplied by the Laboratory Services Division indicated that the sampling done by the private laboratory resulted in a different violation rate.

48 The delivery of the monitoring program for chemical residues by Agency staff during the period 1 April 1999 to 31 August 1999 was assessed in the three operational areas visited. We examined the number of samples obtained, the locations at which the Agency sampled, and the sampling procedure. The results are summarized in the table below.

Analysis of Chemical Residue Monitoring Program Delivery from 1 April 1999 to 31 August 1999 in Three Operational Areas Visited*				
	Area A	Area B	Area C	Total
# Schedules Samples	748	617	491	1,856
# Samples Obtained by CFIA	151	523	210	884
# Importers Visited	15	24	13	52
# Licensed Importers	225	218	83	526
Date Plan Received	30 April 1999	2 June 1999	12 April 1999	
* This table does not contain the samples collected by contracted private laboratories				

We noted that when shipments are sampled, the samples are representative of individual shipment lots. Overall completion of the chemical residue monitoring program by Agency inspectors, in the three areas visited during this five month period, is 48 percent (884/1856), varying from 20 to 85 percent among operational areas. Operational staff received sampling plans after the start of the scheduled sampling period.

49 The Agency claimed that shortfalls in fulfilling the Area workplans during the 1 April 1999 to 31 August 1999 period was due to a lack of fresh fruit and vegetable imports during this sampling period. Consequently, the assessment team reviewed Customs information for a number of selected commodities entering one operational area. This data confirmed the entry into Canada, during the month specified in the Chemical Residue Monitoring Plan, of some commodity/country combinations required by the plan that were not sampled (see Appendix IV). This is another indication to the assessment team that the use of import information could enhance the delivery of the monitoring workplan.

50 Agency inspectors are sampling the produce at a small percentage of importers. They receive no guidance for selecting sampling sites, although the chemical residue monitoring phase is designed to gather information on the occurrence of chemical residues in import shipments chosen at random. We found that monitoring samples obtained by Agency inspectors in three districts visited, were collected at 52 of 526 licenced importers during the period of 1 April 1999 to 31 August 1999. Unlicenced importers were not visited for monitoring sample purposes during this period. The sampling sites used by private laboratories is not known, however, as noted previously, the Laboratory Services Division indicated that the sampling done by private laboratories resulted in a different violation rate. A broader range of imports and importers of fresh fruits and vegetables should be sampled for purposes of monitoring food safety.

51 The scheduled times for sampling commodities from different countries are derived from the Laboratory Services Division's analysis of fresh fruit and vegetable import data. Although the sampling times were not assessed in each operational area, we did analyse the sampling reports for grapes in one operational area to determine whether targeted sampling times and countries were met. Monitoring plans allow for substitution of the scheduled country of origin to compensate for trade patterns. The monitoring samples obtained for grapes were obtained at times other than those recommended by the monitoring plan, and inspectors substituted U.S.A. grapes for grapes from Mexico and Portugal in 29 of the 34 monitoring samples obtained. The results are summarized in Appendix III. It is not known if this situation is common to other commodities or throughout other operational areas; however, it indicates to the assessment team that timely, comprehensive import information could enhance the delivery of the chemical residue monitoring workplan.

52 Import documents or summary reports for fresh fruits and vegetables that have entered Canada are not used to select samples. Inspectors rely on their experience to choose which import establishment to visit, and select monitoring samples by surveying the warehouse. The inspectors have difficulty fulfilling the Chemical Residue Monitoring Plan using this process and, as noted previously, the Agency contracts private laboratories to collect shortfalls. In the monitoring phase, if insufficient information with respect to either the commodity brand or the shipper is recorded on sample forms by Agency inspectors, then surveillance samples cannot be collected for non-compliant products. There is no common understanding of what information and the reason this information must be recorded on the sampling form, when monitoring samples are collected.

Microbiology Sampling Plans

53 Epidemiological information on food-borne disease outbreaks associated with fresh fruits and vegetables is moving concern for the microbiological safety of some imported produce from a low priority to a higher priority. The key objective of the Microbiological Sampling Plans is to identify areas of concern and to take necessary action based on the health risk identified. We reviewed fulfilment of the Fresh Fruit and Vegetable Program's Microbiological Sampling Plans for imported fresh fruits and vegetables.

54 The Microbiological Sampling Plans for 1997-98, 1998-99, and 1999-2000 were fulfilled at a rate of 61 to 86 percent. In plan F207 the Program sampled imported fresh vegetables and pre-cut fresh vegetables for *Staphylococcus aureus*, *Escherichia coli*, *Salmonella*, and *Listeria monocytogenes* each year from 1 April 1997. On 1 April 1999 the Agency added Plan F211 which samples imported fresh fruits for the same pathogenic micro-organisms. An analysis of the national delivery of the sampling plans is summarized in the table below.

Delivery of Sampling Program for F 207 (Fresh and Pre-cut Vegetables) and F211 (Fresh Fruits) Sampling Plans

	F207 97/98	F207 98/99	F207 99/00	F207 Cumulative Totals	F211 99/00
# Samples Scheduled	150	190	150	490	150
# Samples Obtained	108	126	129	363	91
% Program Delivered	72%	66%	86%	75%	61%

The cumulative completion rate for the collection of imported fresh and pre-cut vegetables for microbial analysis is 75 percent. In the operational areas visited we observed that inspectors use the same approach to select shipments for microbiological sampling as is used to select chemical residue monitoring samples.

Consumer Food Products Program

55 We identified the whole fresh fruit, whole fresh vegetable, fresh-cut vegetable and edible nut and seed importing establishments, and determined the number of import establishment inspections conducted by the Consumer Food Products Program and the number of samples obtained. The Agency assessed importers for good manufacturing practices, controls and appropriate information to demonstrate that the food products they import are in compliance with the *Food and Drugs Act and Regulations*. Sampling and analysis of imports must work together with the inspection of importer establishments to demonstrate effective importer control and product compliance.

Importer Inspections

56 All importers subject to inspection were to be included in the Food Establishment List, according to Agency guidelines. We evaluated this database and the inspection summary reports to determine the number of importing establishments and the number of inspections completed. We found that a small percentage of establishments importing whole fresh fruits, whole fresh vegetables, fresh-cut vegetables and edible nuts and seeds, were inspected. Although the Agency could not provide the assessment team with a summary report of imported produce samples taken during importer inspections, our review of importing establishment files indicates that importer inspections were seldom complemented by sampling. The Food Establishment List was not up to date and the information in the database was not always accurate for fresh fruit or vegetable importers.

57 Appendix V presents a summary analysis of the number of importer inspections conducted by the Consumer Food Products Program from April 1997 to November 1999 in the three operational areas visited[3]. The recommended inspection frequency for Risk 1 priority establishments, such as importers of pre-cut vegetables and nuts was every 12 to 18 months. During the period from 1 April 1997 to November 1999 (31 months), 1 out of 17 pre-cut vegetable importing establishments listed in the Food Establishment List was inspected. There were 113 inspections out of 289 nut and seed importing establishments. Operational staff claimed that the number of inspections was low because food safety investigations and emergency response took priority.

[3] Reports from the three operational areas had different end dates in November 1999.

Sampling During Importer Inspections

58 Although there was no schedule for the number of samples to be procured during importer inspections, guidance in terms of specific commodity/hazards of concern was provided. Sampling and analysis are vital to any import control program because the importer's ability to demonstrate compliance can only partially be determined through an inspection. We reviewed the files of 17 importing establishments to determine the number of samples obtained from them since 1 April 1997. We found that four samples (two salads for microbiological pathogens and two nut samples for aflatoxin) had been obtained. The Consumer Food Products Program's work specification for importer inspections indicated that sampling is important because the samples can reflect the conditions under which the product was grown or packaged. The laboratory results showed that three of the four sampled items were unsatisfactory, thus showing that samples taken during inspections can be effective to determine compliance.

59 As mentioned in paragraph 4, the Consumer Food Products Program has now been re-designed and named the Food Safety Investigation Program. As part of the re-design, the Food Safety Investigation Program is implementing a new approach to deliver on its mandate under which it will identify the hazards and risks; identify the current level of control exercised by the industry; determine the risk management strategies which are expected to have the greatest effect on improving the industry's controls to reduce the level of risk; and determine the efficacy of the strategy taken. We are not commenting on the new approach in this assessment. We will assess the effectiveness of this new approach in monitoring and controlling the safety of imported fresh fruits and vegetables during our follow-up to this assessment.

Recommendation

The Canadian Food Inspection Agency should enhance the operational delivery of its chemical residue and microbiological monitoring workplans to ensure compliance with the plans and adequate representation in the selection of samples.

Agency Response

CFIA agrees with the recommendation and has undertaken initiatives designed to improve the implementation of chemical and microbiological monitoring workplans according to program designs. CFIA's chemical and microbiological monitoring functions were transferred into the Bureau of Food Safety and Consumer Protection in 1999. The Bureau has established a number of Science Committees to review and prioritize food safety activities (including monitoring activities) according to level of risk and available resources.

Prioritization of operational activities and deviations from workplan specifications will be addressed through CFIA's quarterly review and reporting process.

Recommendation

The Canadian Food Inspection Agency should ensure that private laboratories contracted to collect samples are provided with guidelines and procedures for collecting and documenting chemical residue monitoring samples. The Agency should investigate any differences in compliance rates between samples collected by Agency staff versus private laboratories.

Agency Response

The CFIA uses private laboratories as an alternate service delivery mechanism to complement CFIA activities. CFIA will provide private laboratories with guidelines and procedures for collecting and documenting chemical residue monitoring samples. CFIA will investigate any significant differences in compliance rates once these procedures have been implemented.

Determining if Non-compliance Has Occurred

General Remarks

60 We reviewed the Fresh Fruit and Vegetable Program's surveillance phases of the Chemical Residue Sampling Plan and of the microbiological sampling plan as these are aimed at verifying suspected potential health hazards identified in the monitoring phases. We also reviewed the Consumer Food Products Program's database of complaints and investigations involving imported pre-cut fresh vegetables, pre-cut fresh fruits, nuts and seeds. We assessed whether the Canadian Food Inspection Agency determined whether a non-compliance had occurred when a potential problem was identified through planned sampling, inspection or other sources such as consumer complaints.

61 Investigations and decisions regarding compliance were made by the Consumer Food Products Program in all food safety incidents we reviewed. In the Fresh Fruit and Vegetable Program's surveillance sampling for chemical residues, we found that a small number (see paragraph 64) of surveillance samples were analysed and products remained on the surveillance list for long periods of time (see paragraph 63). Not all violations from the monitoring program are placed on surveillance; surveillance lists are not regularly sent to inspectors; the procedure of verifying products at destination may allow products on the surveillance list to be imported without sampling.

Fresh Fruit And Vegetable Program

Chemical Residue Surveillance Sampling

62 The Chemical Residue Sampling Plan is divided into three phases: monitoring, surveillance, and compliance. The surveillance phase is designed to verify suspected potential health risks identified in the monitoring phase. In the case of a violation in the monitoring phase, the foreign packer/shipper and/or the foreign country are notified of the result in writing and are expected to implement corrective actions. The specific commodity, brand and shipper is added to a surveillance list, which is distributed to all operational area inspectors. This list is used to identify and sample subsequent shipments of the suspect commodity brand and shipper combination until either five analyses are found acceptable or one is found unacceptable, in which case the product is put on the chemical residue compliance list.

63 The Program's chemical residue surveillance lists from 1 April 1997 to 15 January 2000 implicated 47 commodities, 178 shippers, 22 known countries of origin and 49 different pesticides of concern including 9 commodities with multiple residue concerns. The average time on the surveillance list for the 178 shippers was 26 months. The shortest time was ½ month, which occurred once, and the longest time was more than 60 months, which occurred 21 times. Shippers are automatically removed from the surveillance list 60 months after the last sample tested, even if five compliant shipments have not been collected.

64 A small number of surveillance samples were analysed. In the three districts visited, 45 chemical residue surveillance samples were taken between 1 April to 31 August 1999, with one district collecting 41 of those samples. The 1997-98 chemical residue annual report indicates that there were 169 monitoring phase violations and that 339 surveillance or compliance samples were collected (the chemical residue annual report does not differentiate between the two). In 1998/99 there were 154 monitoring phase violations and 120 surveillance or compliance samples were collected. Import documents can help identify surveillance list shipments for sampling (see paragraph 67).

65 In the Fresh Fruit and Vegetable Program, not all violations of regulatory requirements identified through monitoring are followed up by surveillance actions such as: placing the brand/commodity on the surveillance list; issuing a warning letter to the shipper/grower or embassy/regulatory authority; sampling subsequent shipments; requesting a Health Risk Assessments from Health Canada when required. In the Agency's 1997-98 and 1998-99 chemical residue annual reports, 323 pesticide violations in imported fresh fruits and vegetables were noted. Appropriate surveillance actions were taken on 190 (59 percent) of the violations. In 133 incidents of pesticide residues in excess of the maximum residue levels permitted by the *Food and Drugs Act and Regulations*, action was not taken for reasons including the lack of product grower/shipper information for samples obtained at retail by private laboratories. Consequently, these violations were not added to the surveillance list.

66 The Agency indicated that a significant problem in coordinating the surveillance phase was lack of a timely method of advising area inspectors as to which commodities are on surveillance, how many of the five required samples have been obtained, and which commodities have been removed from surveillance. In 1997-98, the Program issued 13 surveillance lists; the largest gap between lists was three months. In 1998-99, 7 surveillance lists were issued and the largest gap between lists was eight months. During this eight-month gap, shippers and the country of origin were not notified of their violations. Inspectors were not notified of updates to the surveillance list, and consequently surveillance samples for new suspect commodities/shippers were not obtained. The position responsible for coordinating the surveillance program was vacant during these eight months. The Agency indicated that surveillance lists are again being generated on a minimum of a monthly basis. Nevertheless it is possible to inform inspectors of violations soon after violations rather than on the current monthly basis. A gap of one month will shorten the period for sampling the same commodity/shipper combination in the same growing season.

67 The Program does not use import documents to identify commodities on surveillance. Agency officials indicated that import documents do not always contain sufficient information to target the products on the surveillance list. The Agency can amend the information requirements on the Confirmation of Sale documents by modifying legislation or educate the industry to specify the information inspectors require for surveillance sampling on the existing form. Foreign shippers whose products are on surveillance are not compelled to notify the Agency of future shipments. Surveillance samples are gathered by browsing import warehouses during inspections at destination or during collection of monitoring samples. We were informed that it takes at least one hour to review inventory at a large warehouse against the compliance or surveillance lists and since inspectors are very busy, this approach to surveillance sampling was not always practical. At one district office we reviewed Customs import documents and noted five shipments of a commodity that was on the chemical residue surveillance list. The Fresh Fruit and Vegetable Program had not sampled these shipments.

Microbiological Surveillance

68 In principle the microbiological sampling is divided into monitoring, surveillance and compliance phases. Monitoring samples yield information on the microbiological status of food products and identify hazards and risk areas. Microbiological surveillance does not always imply additional sampling but sometimes includes follow-up investigations such as an evaluation of processing, production conditions or requests for health risk assessments by Health Canada, which are managed centrally at the Agency headquarters. Headquarters is routinely notified of positive results by the laboratory, however the Fresh Fruit and Vegetable Inspection Manual contains no written surveillance guidelines or procedures to be followed when violations are identified by microbiological sampling.

Consumer Food Products Program

Incident Investigation

69 We requested information from the Consumer Food Products Program's Incident System documenting complaints, investigations, etc. involving imported pre-cut fresh vegetables, pre-cut fresh fruits, nuts and seeds. We reviewed 1397 incident summaries for three operational areas from April 1997 to November 1999. Imported fresh fruits and vegetables were the subject of 112 of the 1397 incidents reviewed (8 percent). We selected 20 incidents related to food safety to determine whether an investigation was conducted and a subsequent decision regarding compliance made. We found that an investigation and a decision regarding compliance was made in all 20 incidents.

70 Aflatoxin adulteration of nuts and seeds has been identified as a high-risk priority commodity in the Program's work specifications. The Incident System also revealed that imported nuts and seeds from specific countries had been previously identified as being adulterated with excess levels of aflatoxin. We found that two operational areas actively sampled suspect commodity/country imports of nuts and seeds for aflatoxin, while the third area did not take samples because it felt this industry sector had good controls. The Consumer Food Products Program did not have a process analogous to the Fresh Fruit and Vegetable Program's surveillance and compliance lists that can alert inspectors of newly identified high-risk commodities and countries of concern on a frequent, national basis.

Recommendation

The Canadian Food Inspection Agency should improve chemical residue surveillance by:

- ensuring import documents include information that would facilitate their use in identifying shipments for surveillance sampling;
- ensuring that all chemical residue monitoring violations are placed on the surveillance list, and that inspectors are informed of violations as soon as they are known; and
- improving its sampling process to ensure that the required surveillance samples are obtained in a timely manner for all monitoring plan violations.

Agency Response

CFIA is currently investigating changes to fresh fruit and vegetable import documentation requirements. These changes will ensure that import documentation includes the information necessary to identify and track shipments. Implementation of these changes will require that CFIA propose amendments to the *Fresh Fruit and Vegetable Regulations*.

CFIA has taken appropriate steps to ensure that all chemical residue monitoring violations are placed on the surveillance list. CFIA has already implemented procedures to disseminate information to inspection staff. The collection of surveillance samples will be enhanced by improvements to electronic import tracking systems and enhanced working arrangements with the Canada Customs and Revenue Agency, discussed previously.

Recommendation

The Canadian Food Inspection Agency should provide written guidelines and procedures for consistent microbiological surveillance actions in response to non-compliant samples.

Agency Response

The CFIA has recently established the Office of Food Safety and Recall (OFSR) as a single window service to coordinate risk management decisions with respect to food safety issues. All CFIA programs are required to advise the OFSR of violative results as soon as they are available, for assessment and coordination of further action. Where a microbiological standard has been established by Health Canada, OFSR ensures that the appropriate risk management steps are taken. Where no microbiological standard exists, CFIA technical specialists contact Health Canada to request that a Health Risk Assessment be carried out.

The creation of the OFSR is a significant enhancement to CFIA's emergency response structure and will contribute to the overall consistency of CFIA's risk management approach.

Enforcement Actions in Accordance with the Level of Risk

General Remarks

71 We assessed whether the Canadian Food Inspection Agency took consistent and documented enforcement action in accordance with the level of risk when non-compliant fresh fruits or vegetables imports and importers had been identified. We reviewed the enforcement actions taken in situations of non-compliance associated with the Fresh Fruit and Vegetable Program's Chemical Residue and Microbiological Sampling Plans. We analysed the Consumer Food Products Program's inspections of importers with unsatisfactory compliance ratings. We reviewed the enforcement actions taken to control the implicated imported produce and the follow-up actions taken to correct identified problems and to prevent future problems. Although the intention is to confirm that products with a history of non-compliance with Canadian standards for chemical residues are satisfactory prior to their release in Canada, the present system's weaknesses, described below, may not allow for effective controls.

Fresh Fruit and Vegetable Program

Chemical Residue Compliance Phase

72 The compliance phase of the Chemical Residue Sampling Plan is designed to prevent the marketing of products with a history of non-compliance. As these products are considered high-risk for violation of Canadian standards for chemical residues, the next five shipments must be accompanied by a certificate of analysis confirming the commodity's compliance with Canadian regulations, or the Agency will detain the shipment for testing at the expense of the importer prior to release to the Canadian marketplace. Otherwise, the Agency will instruct Customs to refuse the shipment entry into Canada. Non-compliant products are to be either returned or destroyed. The compliance phase is coordinated by the Agency Headquarters staff. The foreign packer/shipper and/or the foreign country is notified by letter of the commodities found to have a history of chemical residue violations. The specific commodity, brand and shipper is added to a compliance list, which is distributed to operational area staff for use in implementing the compliance phase.

73 Between 1 April 1997 and 25 November 1999, compliance lists were issued at essentially the same frequency, and with the same gaps as noted for surveillance lists (see paragraph 66). Thirty-one shippers were on the compliance list for an average of 28 months or longer. The shortest period of time on the compliance list was one month, which occurred in four cases. The longest was 60 months, which occurred seven times. Shippers are also automatically removed from the compliance list 60 months after the last sample tested. The period of time commodities remain on the compliance list is slightly longer than the period of time they remain on surveillance lists. The Agency may not be able to identify the next five shipments with the current import control process.

74 Border Lookouts are not used to alert Customs and Agency inspectors to the arrival of produce with a history of non-compliant levels of chemical residues, as is currently required by the Fresh Fruit and Vegetable Inspection Manual (refer to Paragraphs 27 and 29 for Border Lookout criteria). Import documents are not used to identify commodities on the compliance list. The arrival of the next five shipments of products on a compliance list is monitored by inspectors surveying import warehouses during product quality inspections or during collection of monitoring samples, similar to the process for surveillance samples. Foreign shippers of products placed on a compliance list are not required to notify the Agency of the arrival of future shipments.

75 We noted that between 1 April 1999 to 31 August 1999 there were 18 shippers of commodities with a history of excess levels of pesticides identified on the Fresh Fruit and Vegetable Program's chemical residue compliance list. During this time, 12 compliance samples were taken in one operational area, and none in the other two areas.

76 We interviewed Fresh Fruit and Vegetable Program operational area inspectors and reviewed compliance files to determine the number of shippers that voluntarily supplied certificates of analysis as confirmation of compliance of shipments to Canadian regulations. We found that certificates of analysis accompanied 3 of 9 shippers of commodities on the compliance list and the other six commodities were detained for analyses or returned to the country of origin or disposed of. When shipments of imported fresh fruits or vegetables do arrive with certificates of analysis from foreign countries, the Fresh Fruit and Vegetable Inspection Manual requires a copy of the certificate to be forwarded to Headquarters; depending on the history of the certificate, the inspector is advised to either obtain a verification sample or release the lot. The Agency does not accredit foreign laboratories but does verify foreign certificates of analysis in accordance with written procedures.

77 While the harm posed by microbiological contaminants is acute and manifested in immediate illness, the harm posed by excess chemical residues is chronic or long-term and is not easily measured or traced. While there is a clearer connection between microbiological contamination and food-borne illness because of available quantitative epidemiological data, this does not mean that the risk associated with excess chemical residues is any less significant. When microbiological pathogens are found, regulatory action —such as prevention of further distribution, recall from the marketplace and product disposal— is taken to protect the Canadian consumer from the immediate hazard. Similar recall actions are taken for chemical residues when the excess residue limits present an immediate health hazard. However, no action is taken to prevent the further distribution and subsequent sale of products when only a long-term risk exists, for example when surveillance samples were found to violate the maximum residue limits.

Microbiological Sampling Compliance Phase

78 The microbiological sampling program has not developed written compliance guidelines to address such issues as the use of Border Lookouts or compliance lists to notify inspectors and target sampling of future shipments. Each incident is dealt with individually. We found two cases, involving coleslaw in 1997-98 and garden salad in 1999-2000, where microbiological sampling identified pathogenic bacteria (*Listeria monocytogenes*) in imported pre-cut vegetables. In one case, follow-up consisted of an investigation by the foreign regulatory agency at the processing establishment and subsequent shipments of the suspect product were sampled. These products were not placed on Border Lookout to assist in targeting future shipments for sampling.

Consumer Food Products Program

Importer Inspections

79 The Consumer Food Products Program rated the compliance of each import establishment inspected. The compliance status was part of the criteria used to establish the priority for inspections and was also used in the scheduling of follow-up inspections of non-compliant importers. We reviewed import establishment summary inspection reports for the assessment period of April 1997 to November 1999, and identified all the establishments with an unsatisfactory compliance rating. We determined whether follow-up inspections had been completed according to the noted re-inspection date. Twenty nut and seed importing establishments across the three operational areas were inspected and assigned an unsatisfactory compliance rating. Eight re-inspections were completed as planned (40 percent), 10 establishments had not been re-inspected (50 percent) and two re-inspection dates were scheduled after our examination.

Product Sampling

80 The Consumer Food Product Program sampled imported nuts and seeds for aflatoxin contamination in two of three operational areas visited. One of these areas issued an Area Border Lookouts for all importers of pistachio nuts because these products had a history of non-compliance in their area. The Program did not have any national Border Lookouts for pre-cut fresh vegetables, or for nuts and seeds.

Recommendation

The Canadian Food Inspection Agency should improve its chemical residue compliance process by:

- using Border Lookouts, import information or other means to identify the next five imported fresh fruit and vegetable shipments for commodities on the chemical residue compliance list (those that exceeded accepted Canadian standards in the surveillance phase) and ensuring that these shipments are certified as meeting Canadian requirements prior to release in Canada; and
- taking action to prevent the further distribution for sale of imported fresh fruits and vegetables that exceed maximum residue limits.

Agency Response

As noted previously, improved electronic tracking systems and updated procedures with the Canada Customs and Revenue Agency should improve CFIA's ability to identify compliance samples. CFIA's National Policy on Border Lookouts specifies that these activities are intended to be used as an exceptional measure to address an immediate high risk situation. CFIA will continue to use border lookouts when a product has been identified as a high risk health hazard for Canadians and will target lookouts appropriately for increased effectiveness and efficiency.

Incidents in which fresh fruits and vegetables are confirmed to exceed maximum residue limits will be assessed by the Office of Food Safety and Recall to determine appropriate action and to prevent further distribution. As well, the CFIA has recently taken steps to publish on its website the names of the responsible parties that have had their product found in violation of the required limits to encourage importers to source produce that meets Canadian requirements.

Trace-back Investigations in Fresh Fruit and Vegetable Food-borne Disease Outbreaks

Fresh Fruit and Vegetable Program and the Consumer Food Products Program

81 The ability of both the Fresh Fruit and Vegetable Program and the Consumer Food Products Program to trace-back products – including imported produce – to the source of production can be a key element of public health protection. Adequate procedures, documentation and expertise are required to conduct trace-backs quickly. We assessed whether the Agency provides written procedures and training for trace-back investigations. Since the creation of the Agency, a number of imported fresh fruits and vegetables have been epidemiologically linked to Canadian and international outbreaks of illness. We reviewed five food-borne disease outbreaks associated with imported fresh fruits and vegetables, and analysed the Agency's response.

82 We found that the officials of both the Fresh Fruit and Vegetable Program and the Consumer Food Products Program were key members of the investigative team, and that they participated in trace-back investigations and took the lead role in communicating with importers, other regulatory agencies, and embassies. They acted as the liaison for import information on the implicated products, and they initiated import controls such as Border Lookouts. Follow-up actions included: requesting for health risk assessments; holding post mortems; assessing foreign countries; implementing new import policies or controls; and implementing new or redesigned programs or strategies.

83 In November 1997, the U.S. Food and Drug Administration advised Guatemalan officials that they would not allow the importation of raspberries from Guatemala during the 1998 spring shipping season. On 16 March 1998, officials of the Canadian Food Inspection Agency and Health Canada met with officials of the Guatemalan Embassy and with Guatemalan technical experts to obtain specific information on the measures being taken to minimize the microbial risks associated with *Cyclospora* in raspberries. Agency and Health Canada officials visited Guatemala between 30 March and 7 April 1998 to evaluate the Guatemalan inspection system and to assess the potential microbial risks. At the time of the visit, the Guatemalan inspection system classified raspberry farms in three risk categories (low, medium and high), reflecting the degree of preventative measures taken on the farm. At that time, Canadian authorities allowed the importation of fresh Guatemalan raspberries produced from low-risk farms. In May 1998, Guatemalan officials introduced a new category (the Model Plan of Excellence) with a more stringent degree of preventative measure and a system to trace back products to the source of production. By the time that Canadian officials finalized their import position, several outbreaks of *Cyclosporiasis* had occurred in Ontario. We found that Canadian Food Inspection Agency and Health Canada officials are working to establish timely Canadian policies for the seasonal importation of Guatemalan raspberries. The policies include measures to verify that their recommendations are being implemented by Guatemalan growers, shippers and regulatory agencies.

84 We found that a trace-back investigation was conducted in each food safety situation that required one. The United States Centre for Disease Control provided expertise and guidance to Canadian investigators, along with specific forms. The Agency has prepared a draft trace-back manual. Operational area staff had concerns regarding who within the Agency should conduct trace-back investigations, the roles and responsibilities of other regulatory agencies, the level of detailed work required, and the availability of training in food safety. The Agency informed us that training for trace-back investigations is planned after the trace-back manual is completed.

Conclusions

85 The following points summarize our conclusions with respect to the criteria used for the assessment (see "About the Assessment"). Improvements can be made that will provide a greater level of assurance that consumers are protected from hazardous imported fresh fruits and vegetables.

Program Planning: The Canadian Food Inspection Agency estimated the risks associated with imported fresh fruits and vegetables and provided operational staff with sampling and inspection plans that target prioritized importers and imported produce.

Program Design: The two Agency programs involved in the control of imported fresh fruits and vegetables used different control strategies. Both programs were implementing new strategies to address emerging issues in imported fresh fruits and vegetables. The Agency is working towards integrated import control strategies.

Use of Import Documentation: The Canadian Food Inspection Agency can make better use of import information in its programs and activities including in food safety sampling, inspection and investigations. A reliable method for collecting and using information on fresh fruit and vegetable imports, especially those with a history of non-compliance, would greatly improve many aspects of the program delivery and the overall effectiveness of the food safety activities. The Agency has devoted much effort to developing an electronic information processing system - Import Control and Tracking System - that eventually will be available to all commodities, including fresh fruits and vegetables.

Program Delivery: The Fresh Fruit and Vegetable Program collects and analyses thousands of imported fresh fruits and vegetables each year for chemical residues and microbiological pathogens. The workplans are partially met by the operational areas and, in the case of chemical residues, supplemented by private laboratories to further fulfill the sampling requirements. Better collection of samples in accordance with workplans requirements and collection at more destination points is possible.

The Consumer Food Products Program inspected fresh fruit and vegetable importing establishments. It supplemented the inspections with sampling of suspected non-compliant products to evaluate the conditions under which the product was grown or packaged. The coverage of high-priority commodity importers was not appropriate. A small number of importing establishments were inspected and these inspections were seldom complemented by sampling. Following an Agency program review this program was re-designed and re-named the Food Safety Investigation Program.

Determining if Non-compliance Has Occurred: The surveillance phase of the Fresh Fruit and Vegetable Program's chemical residue needs improvement. Monitoring-phase violations were not always followed by surveillance actions. Inspectors need to be informed promptly of the status of commodities and shippers on the surveillance list and focus on determining the compliance status of future shipments. Improved methods for identification of these shipments would be beneficial.

The Consumer Food Products Program appropriately investigated and determined the compliance status of food safety incidents (e.g., consumer complaints) related to imported fresh fruits and vegetables.

Enforcement Actions: Improvements are needed in the compliance phase of chemical residue sampling to prevent the importation of a commodity with a history of non-compliance, unless there is certification that the shipments meet Canadian requirements. Because foreign shippers are not required to notify the Agency of the arrival of future shipments, more frequent use of Border Lookouts or access to timely import information are needed to identify shipments of commodities on the compliance list. The Fresh Fruit and Vegetable Program should take action to prevent the further distribution of imported fresh fruits and vegetables that exceed maximum residue limits. The Agency verifies foreign certificates of analysis in accordance with their written procedures.

The Consumer Food Products Program did not re-inspect importer establishments that had received an unsatisfactory compliance rating as planned.

Trace back Investigations: When there is notification of a food-borne disease outbreak associated with imported fresh fruits and vegetables, officials of both programs become key members of the investigative team. The continuing ability of staff from both programs to trace-back imported produce to the source of production is a key element of public health protection. The Agency has written draft procedures for trace-back investigations, and training of inspectors is planned after the trace-back manual is completed.

86 In summary, various aspects of the Fresh Fruit and Vegetable Program and the Consumer Food Products Program were working as intended, however, some key improvements are required in order to increase their effectiveness. In particular, improving the access to and use of available information on imported products, especially those with a history of non-compliance, as they enter Canada would clearly lead to increased assurance in the safety of imported fresh fruits and vegetables.

Appendix I

About the Assessment

Objective

To determine the effectiveness of the Canadian Food Inspection Agency's programs and activities related to the safety of imported fresh fruits and vegetables.

Criteria:

The criteria against which the Agency's programs and activities were assessed, are:

1. Does the Canadian Food Inspection Agency design and implement Programs and activities which effectively monitor the safety of imported fresh fruits and vegetables?

    1.1 Does the Canadian Food Inspection Agency estimate the risk of identified hazards in imported fresh fruits and vegetables, develop risk management options, and establish priorities for managing the food safety risks, in each applicable Program?

    1.2 Does the Canadian Food Inspection Agency design Programs and plan activities to cover their applicable legislative requirements and control the safety of imported fresh fruits and vegetables?

    1.3 Does the Canadian Food Inspection Agency forward fresh fruit and vegetable import documents to inspection staff and use them to select imported produce for sampling and identify importing establishments for inspection?

    1.4 Does the Canadian Food Inspection Agency sample fresh fruit or vegetable shipments and inspect importing establishments in accordance with the level of risk and work plan requirements?

2. Where non-compliance with legislative requirements or recognized standards is identified, does the Canadian Food Inspection Agency take appropriate enforcement action to control unsafe imported fresh fruits and vegetables?

    2.1 Where notified of a potential problem, does the Canadian Food Inspection Agency determine whether non-compliance has occurred?

    2.2 Where non-compliance has been identified, is consistent, documented enforcement action taken in accordance with the level of risk?

    2.3 Does the Canadian Food Inspection Agency provide written procedures and training for trace-back investigations?

2.4 Where certificates of analysis are used to confirm the compliance of imported fresh fruits and vegetables, does the Canadian Food Inspection Agency verify laboratory accreditation and analytical results?

Scope and Approach

We examined programs and activities related to the safety of imported fresh fruits and vegetables between 1 April 1997 and 31 March 2000. The scope included whole fresh fruits and vegetables, pre-cut fresh fruits and vegetables, and nuts. We met with key personnel at Canadian Food Inspection Agency Headquarters and in three operational areas (Quebec, Ontario and Western) and reviewed the program planning and co-ordination, the program workplans, the program manuals and available files. We visited three of the busiest ports of entry in Canada, interviewed Customs officials and observed the handling of import documents and Border Lookouts. We reviewed the flow of information from the ports of entry to the Canadian Food Inspection Agency and the use of this information in program planning and delivery.

In each of the three operational area we visited, we analysed the delivery of the sampling programs for chemical residues and microbiological pathogens by reviewing operational area workplans and results, and interviewing Agency inspectors. We discussed the selection of monitoring, surveillance and compliance samples and assessed the coverage of importers within each district visited. We evaluated the collection of samples by inspectors by observing inspectors during visits to three produce warehouses. We analysed surveillance lists and compliance lists to evaluate the effectiveness of the strategies for surveillance, investigation and enforcement.

The Consumer Food Products Program provided the assessment team with summary reports on importer establishments, importer inspections, samples obtained, and incidents such as consumer complaints. We interviewed inspection staff in three district offices visited and reviewed and analysed the summary reports and associated operational files to determine whether the importers of fresh fruits and vegetables were being inspected and whether samples were obtained during the inspections. We selected and reviewed 20 incidents related to food safety and determined whether an investigation and a subsequent decision regarding compliance was made. We also reviewed files associated with potential problem situations and non-compliance situations involving illness outbreaks, recalls, microbiological pathogens, chemical residues and consumer complaints and interviewed inspectors.

This assessment was undertaken according to the mandate defined in the *Canadian Food Inspection Agency Act*. Section 11 (4) of the Act specifies: "The Minister of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency's activities related to food safety." Therefore the assessment role of the Minister of Health, as defined in the Act, covers the Agency exclusively and does not include other federal organizations. Our scope reflects this legislative provision.

Assessment team:

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Appendix II

Legislative Authority and Requirements

The Canadian Food Inspection Agency is responsible for monitoring compliance with and enforcing the food safety requirements in the *Food and Drugs Act* as it relates to food, the *Consumer Packaging and Labelling Act*, and the *Canada Agricultural Products Act*.

The *Food and Drugs Act*, section 4. states:

> No person shall sell an article of food that
>
> a. has in or upon it any poisonous or harmful substance;
> b. is unfit for human consumption;
> c. consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
> d. is adulterated;
> e. was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

"Unsatisfactory conditions" means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic.

The *Food and Drug Regulation*, section A.01.040 requires that no person shall import into Canada for sale a food, the sale of which in Canada would constitute a violation of the Act or Regulations.

The *Canada Agricultural Products Act*, section 17, contains a similar requirement to the *Food and Drug Regulation* section A.01.040. Section 17 states:

> No person shall, except in accordance with this Act or the regulations,
>
> a. market an agricultural product in import, export or interprovincial trade;
> b. possess an agricultural product for the purpose of marketing it in import, export or interprovincial trade; or
> c. possess an agricultural product that has been marketed in contravention of this Act or the regulations."

The *Fresh Fruits and Vegetables Products Regulations* section 3.1(1) requires that: "no person shall market any produce in import trade as food unless it:

> a. is not adulterated;
> b. is not contaminated;
> c. is edible;
> d. is free of any live insect, scorpion, snake, spider or other living thing that may be injurious to health;
> e. is prepared in a sanitary manner;

f. where irradiated, is irradiated in accordance with Division 26 of Part B of the *Food and Drug Regulations*;
g. meets all other requirements of the *Food and Drugs Act* and the *Food and Drug Regulations* with respect to the produce
h. meets the requirements of the *Plant Quarantine Act* and the regulations made under that Act.

"***Prepared in a sanitary manner***," for the purposes of 3.1(1)e, includes preparation in such a manner that:

a. no stagnant or polluted water is used in the washing or fluming of the produce;
b. only potable water is used in the final rinsing of the produce to remove any surface contaminant before packing;
c. the final rinse water, if reused, is only in the initial washing or fluming of the produce; and
d. the produce is handled with equipment that is cleaned regularly.

"***Adulterated***," in respect of produce, means adulterated within the meaning of sections B.01.046 and B.01.047 and Division 15 of Part B of the *Food and Drug Regulations*.

"***Contaminated***," in respect of produce, means containing a chemical, drug, food additive, heavy metal, industrial pollutant, ingredient, medicine, microbe, pesticide, poison, toxin or any other substance not permitted by, or in an amount in excess of limits prescribed under, the *Canadian Environmental Protection Act,* the *Food and Drugs Act* or the *Pest Control Products Act*.

"***Edible***" means fit for use as food.

"***Produce***" means any fresh fruit, fresh vegetable, nuts or edible fungi.

Appendix III

Selection of 34 Scheduled Grape Chemical Residue Monitoring Samples in One Operational Area Between 1 April 1999 – 31 August 1999

Samples / Country Targeted	Samples / Country Collected
21/34 samples targeted for Mexico	4/21 samples from Mexico collected
12/34 samples targeted for Portugal	0/12 samples from Portugal collected
1/34 samples targeted for USA	1/1 sample from USA collected 29 samples from USA substituted for Mexico and Portugal sample targets
34 samples targeting 3 countries	34 samples collected from 2 countries 29 substitution samples

Number / Month Scheduled	Number / Month Obtained
10 samples scheduled to be collected in April	4 samples obtained in June 6 samples obtained in September
11 samples scheduled to be collected in May	4 samples obtained in September 7 samples obtained in October
1 sample scheduled to be collected in June	1 sample obtained in June
12 samples scheduled to be collected in July	6 samples obtained in September 6 samples obtained in October
34 samples scheduled for April to July	34 samples obtained between June to October

Appendix IV

Analysis of the Availability of Selected Commodities during 1 April to 31 August 1999 in One Operational Area

(does not include samples collected by private laboratories)

Commodity	#Scheduled - Country	Entry Confirmed	Samples Collected by Agency Inspectors
Nectarines	7 - USA	Yes	0
Carrots	5 - USA	Yes	0
	5 - Mexico	No	0
Lettuce	17 - USA	Yes	0
	3 - Mexico	No	0
Corn	15 - USA	Yes	0
	6 - Mexico	Yes	3
	10 - Mexico	No	0
Berries[1]	4 - USA	Yes	0
	2 - Chile	Yes	0
	2 - Guatemala	Yes	0
	2 - Mexico	No	0
	4 - Mexico	Yes	0
	1 - USA	No	0

[1]The Canada Customs codes do not distinguish between blackberries and raspberries.

Appendix V

Consumer Food Products Program Importer Establishment Inspection – April 1997 to Nov 1999 for Three Operational Areas Visited

Importer Establishment Type	Area A	Area B	Area C	Totals
	# Inspections / # Importers	# Inspections / # Importers	# Inspections / # Importers	# Inspections / # Importers
Fresh Fruit Importer - risk priority 4, recommended inspection frequency 60 months	7/71	6/112	2/135	15/318
Fresh Vegetable Importer - risk priority 2, recommended inspection frequency 36 months	2/76	6/98	3/143	11/317
Pre-cut Vegetable Importer - risk priority 1, recommended inspection frequency 12 -18 months	0/2	1/3	0/12	1/17
Nut and Seed Importer - risk priority 1, recommended inspection frequency 12 -18 months	28/57	60/137	25/95	113/289
# Inspections of Combined Commodity Importer	8	14	2	24
Totals - # Inspections / # Importers	45/206	87/350	32/385	164/941